



PATENT
Attorney Docket GENE-106/02US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **CASTLE et al.**)
Application No.: **10/633,306**) Group Art Unit: **1631**
Filed: **August 4, 2003**) Examiner: **Marina Miller**
For: **Methods for Classification**)
 of Biological Data)

Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
Customer Window, Mail Stop – AMENDMENT
Randolph Building
401 Dulany Street
Alexandria, VA 22314

RESPONSE TO RESTRICTION REQUIREMENT UNDER 37 C.F.R. § 121

This paper responds to the Restriction Requirement dated September 19, 2005. A petition for a three-month extension of time is submitted herewith, extending the period from October 19, 2005 to January 19, 2005.

On September 19, 2005, the Patent Office issued a Restriction Requirement on the claims of the present application. The Patent Office has concluded that the application encompasses two distinct inventions:

Group I, Claims 1-17, drawn to a method for identifying marker genes whose level of expression predicts a biological response.

Group II, Claims 18-19, drawn to a method of building a classification database.

Applicants hereby elect to prosecute the claims of Group I (claims 1-17, drawn to methods for identifying marker genes whose level of expression predicts a biological response) with traverse.

The Manual of Patent Examining Procedure (MPEP) states that

“Under the statute an application may properly be required to be restricted to one or more claimed inventions only if they are able to support separate patents, and they are either independent (MPEP § 806.04 .§ 806.04(i)) or distinct (MPEP § 806.05 § 806.05(i)).”

The MPEP further states that "Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the requirement in most cases." MPEP § 803 (Guidelines). "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits..." MPEP § 803. For purposes of the initial requirement "a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classifications, separate status in the art, or a different field of search as defined in MPEP § 808.02." MPEP § 803 (Guidelines). Applicants respectfully submit that the Patent Office has not met even the aforementioned initial requirement. The Patent Office has not shown or explained that the alleged separate inventions fall into separate classifications, have a separate status in the art, or would require different fields of search. On the contrary, no separate search is required as both Groups I and II belong to class 72, subclass 19. Therefore, the Patent Office has completely failed to meet its burden to show that the claims require restriction. For all of the foregoing reasons, Applicants traverse the restriction requirement, and request restriction be withdrawn.

With regard to species elections, Applicants elect, with traverse, the species of:

Specie A: the magnitude of the difference in gene expression.

Specie B: population stratified for its response.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

COOLEY GODWARD LLP

Date: January 19, 2006

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